



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request Information Program on the Genetic Testing Registry

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Request for comments

SUMMARY: Under the provisions of Section 3507(a) (1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on July 27, 2011, (76 FR 44937) and allowed 60 days for public comment. Twelve public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Genetic Testing Registry; *Type of Information Collection Request:* New collection; *Need and Use of Information Collection:* Laboratory tests for more than 2,000 genetic conditions are available; however, there is no centralized public resource that provides information about the availability and scientific basis of these tests.

Recognizing the importance of making this information easily accessible to health care providers, patients, consumers, and others, NIH is developing a voluntary registry of genetic tests. The Genetic Testing Registry (GTR) will provide a centralized, online location for test developers, manufacturers, and researchers to submit detailed information about genetic tests. The overarching goal of the GTR is to advance the public health and research in the genetic basis of health and disease. As such, the Registry will have several key functions, including (1) encouraging providers of genetic tests to enhance transparency by publicly sharing information about the availability and utility of their tests; (2) providing an information resource for the public, including health care providers, patients, and researchers, to locate laboratories that offer particular tests; and (3) facilitating genetic and genomic data-sharing for research and new scientific discoveries.

Frequency of Response: The information will be submitted voluntarily on a non-repeating, continual basis. Submitters will be requested to update their test information at least once every 12 months.

Respondents: Submitters to the GTR are expected to include clinical laboratories, researchers, and entities that report and interpret tests performed elsewhere. The GTR is not limited to U.S. respondents; it will also include submissions from outside the United States. Information will be collected and managed using an online submission system.

Estimate of Burden: Although participation in the GTR is voluntary, in order to participate, respondents must provide information for a certain subset of fields, identified as the “minimal fields.” GTR includes 31 minimal fields and 85 optional fields. Sixteen of the 31 minimal fields refer to contact data and other information about the laboratory, which the respondent completes only once. These data will autopopulate new test records, leaving 15 minimal fields that require completion. The GTR will also support bulk submission as an XML file or uploading subsets of information from spreadsheets, which will significantly reduce the burden for laboratories that want to provide information on multiple genetic tests. The annualized cost to respondents is estimated at \$1,103.

Estimates of Hour Burden

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Laboratory Personnel	770	12	Minimal Fields: 0.5 Optional Fields: 2.5	Minimal Fields: 4,620 Optional Fields: 23,100
Total	770		3.0	27,720

Request For Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instrument, contact: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH, by mail to the Office of Biotechnology Activities, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892; telephone 301-496-9838; fax 301-496-9839; or email gtr@od.nih.gov; or refer to the GTR website at <http://oba.od.nih.gov/gtr/gtr.html>.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: November 16, 2011

Amy P. Patterson, M.D.
Associate Director for Science Policy, NIH

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